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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,890	06/28/2006	Jason D. Bonk	59136US010	1920
23628	7590	05/10/2010	EXAMINER	
WOLF GREENFIELD & SACKS, P.C. 600 ATLANTIC AVENUE BOSTON, MA 02210-2206				DESAI, RITA J
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
05/10/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,890	BONK ET AL.	
	Examiner	Art Unit	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 17 February 2010.
 2a) This action is **FINAL**. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-9 and 11-16 is/are pending in the application.
 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 2-9, 11-13 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Claims pending 2-9, 11-16.

Claim 10, 17 and 18 are cancelled.

Claims 14-16 are withdrawn.

Response to the arguments:-

The rejection of claims 2-9, 11-13 under 35 USC 112 scope of enablement still stands.

Applicants have not amended the claims to overcome the rejection.

Applicants argue that the specification enables one of skill in the art to make and use the compounds of the invention. The scheme has been given on page 25-28 and examples on pages 32-56. This is not convincing. All the examples have R1 to be a phenyl, n to be 0.

There is no reduction to practice , commensurate to the scope of the claims let alone the activity.

Genetech Inc Vs Nova Nordisk 42 USPQ 2d 1001.

“A patent is not a hunting license. It is not a reward for search but compensation for its successful conclusion and patent protection is granted in return for an enabling disclosure of an invention , not for vague intimations of general ideas that may or may not be workable.”

Also see *Ex parte DIAMOND*, 123 USPQ 167 (Bd. Pat. App. & Int. 1959) where the examiner was affirmed for a scope of enablement rejection, and the court stated:

Scope of claims should not be unduly extensive in chemical fields where applicability is highly speculative or not explored; subject matter which relies upon prediction for its support is unpatentable.

Specification contains 23 specific examples, but they are to preparation of relatively simple compounds; this is relatively meager and non representative disclosure to support claims embracing millions of compounds.

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Applicant may not preempt unduly large field by expedient of making broad prophetic statements in specification and claims unless accuracy of such statements is sufficiently supported by well established chemical principles or by sufficient number of examples. “The term ‘substituted’ without modification or restriction includes all compounds wherein one or more of the atoms or radicals of the original compound have been replaced by one or more other atoms or radicals. Without any limitation on the character or number of substituents it becomes apparent that the quoted term may be considered inclusive of almost any possible substance and the claims under consideration are either of unlimited or indeterminate scope. We are of the opinion that the reasoning of the courts in Schering Corp. v. Gilbert, 68 USPQ 84, and Hercules Powder Co. v. Rohm & Haas, 70 USPQ 297, is controlling.” embrace millions of compounds. It should also be observed that appellant is working in a field where little prediction is possible and this Board has on several occasions held that the scope of claims should not be unduly extensive in fields where applicability is highly speculative or not explored and that subject matter which relies upon prediction for its support is unpatentable. Ex parte Middleton, 87 USPQ 57; Ex parte Kauck et al., 95 USPQ 197, Ex parte Rosenkranz et al., Pat. No. 2,715,637. In Minnesota Mining and Mfg. Co. et al. v. Carborundum Co. et al., 155 F.2d 746, 69 USPQ 288, the court held that “An inventor cannot disclose a small number of components which will serve as a springboard for claiming an entire class.”

In addition *In re Fouche* 169 USPQ 429 dealt with a similar issue with respect to how to use requirement of 112 1st paragraph,

“Inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention; nevertheless, applicant must use some technique of providing teaching of how to use which is commensurate with breadth of protection sought by claim, unless such knowledge is already available to persons skilled in the art; thus, where applicant undertakes to define invention by recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of group.

Both the examiner and the board noted that none of the working examples pertained to compounds wherein Z was heterocyclic. Appellant is quite correct in contending that, under our decisions in *In re Robins*, 57 CCPA 1321, 429 F.2d 452, 166 USPQ 552 (1970), the inclusion of representative examples is not required to enable a person skilled in the art to use a generic invention. Nevertheless, an applicant must use *some* technique of providing teaching of how to use which is commensurate with the breadth of protection sought by the claim, unless such knowledge is already available to persons skilled in the art.

It seems clear, and it is not disputed by appellant, that where an applicant undertakes to define his invention by the recitation of a Markush group, he must enable one skilled in the art to make and use at least one composition employing each member of the Markush group. The examiner and the board did not believe that appellant had done so as to the heterocyclic members of the group. While they noted the absence of examples using heterocyclic moieties, we do not find that

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they viewed examples as mandatory. The issue before us is whether appellant has provided *any* teaching of how to use compounds containing the heterocyclic members of the Markush group. The only reference to heterocyclic radicals in the specification is the statement that “the invention provides” compounds of the structure shown in claim 1, wherein Z may be, among other possibilities, a mononuclear, nitrogen-containing heterocycle connected to the chain A by the nitrogen atom, and optionally containing an oxygen, sulphur, or second nitrogen atom in the ring and optionally substituted by one of more alkyl radicals containing 1 to 5 carbon atoms each, such as 1-pyrrolidyl, piperidino, morpholino, 1-piperazinyl, or 4-alkyl-1-piperazinyl. “

See *Ex parte WEIL AND SCHLICHTING*, 158 USPQ 620 (Bd. Pat. App. & Int. 1967)

“We will sustain this rejection of the claims as we are in accord with the examiner's position. We find no support in the disclosure for such compounds encompassed by these claims wherein R 1, R 2, R 3, and R 5 are all the same and selected from the group, lower alkyl , hydroxy , alkoxy , di(loweralkyl)amino and nitro for example. These claims appear to be in the nature of a paper concept wherein all possible substituents have been included in the composition. There are no examples of such compounds which are included within the vast scope encompassed by these claims, although appellants have a considerable disclosure with respect to certain components but this does not warrant claims of the enormous breadth recited.”

See also: *Schering Corporation v. Gilbert et al.*, 68 USPQ 84 (2d Cir. 1946)

It was shown in evidence and by way of admissions elicited by the defendants from the plaintiff before trial that one skilled in the art of organic chemistry may start in the group of the acetic acid radical and the radicals of homologues of acetic acid to which the patent relates, for instance, with the simple hydrocarbon called methane and theoretically progress along the series in the general group called alkanes from one substance to another by increasing the size of the molecules in steps of one carbon atom and two hydrogen atoms. At least formulas for such substances, as well as for others, can be written in an indefinite chain. Also it was shown that for the hydrogen atoms of the alkane molecules the atoms of what are called halogens may be substituted and so may the atoms of other groups including the residue of the hydrocarbon benzene. The latter is represented in chemical formulas by a hexagon which is called the benzene ring and, as changes in the atomic structure of the molecule occur, the ones introduced take varying positions within the ring which positions determine the nature of the compound. Theoretically a multitude of substances not as yet found in nature and not as yet compounded could be synthesized, if skilled organic chemists were given the time and materials with which to work, and actually the formulas for them could be written. There is, however, a practical limit upon synthesis, though the extent of that is not fully known, for some of the new theoretical compounds might be impossible to create, and some would be so unstable that they would disintegrate either at once or in short periods of varying length. Moreover, while analogy is at times useful, organic chemistry is essentially an experimental science and results are often uncertain, unpredictable and unexpected.

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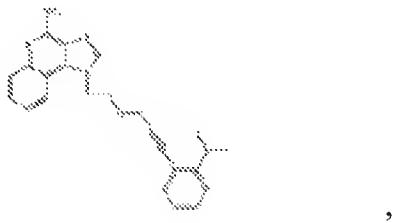
The rejection of the claims under 35 USC 103 also still stands.

Applicants are arguing the rejection piecemeal basis.

Gerter teach the same core of the compounds.

Charles Leslie and Dellaria example 7 does teach similar compounds with an alkyl chain interrupted by an O and further having an unsaturated chain.

Example 7 of Dellaria '372



Gerter '051 teaches the same core and various R1 linkages, Amongst which is an alkenyl group which is substituted by an aryl.

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wherein

R_1 is $=\text{N}(\text{R})=\text{CR}=\text{CR}=\text{C}\text{R}=\text{N}$; $=\text{CR}=\text{N}=\text{CR}=\text{C}\text{R}=\text{N}$; $=\text{CR}=\text{CR}=\text{N}=\text{CR}=\text{C}\text{R}=\text{N}$; or $=\text{CR}=\text{CR}=\text{C}\text{R}=\text{C}\text{R}=\text{N}=\text{C}\text{R}=\text{C}\text{R}=\text{N}$

R_1 is selected from the group consisting of:

- hydrogen;

- C_{1-20} alkyl or C_{2-20} alkenyl that is unsubstituted or substituted by one or more substituents selected from the group consisting of:

- aryl;

- heteroaryl;

- heterocyclyl;

- $\text{O}-\text{C}_{1-20}$ alkyl;

- $\text{O}-\text{C}^{\text{a}}(\text{R})_{2-}\text{alkyl}$, $\text{O}-\text{aryl}$;

- $\text{O}-\text{C}^{\text{a}}(\text{R})_{2-}\text{alkyl}$, $\text{O}-\text{heteroaryl}$;

- $\text{O}-\text{C}^{\text{a}}(\text{R})_{2-}\text{alkyl}$, $\text{O}-\text{heterocyclyl}$;

- C_{1-20} alkoxycarbonyl;

- $\text{S}(\text{O})_{0-2}-\text{C}_{1-20}$ alkyl;

- $\text{S}(\text{O})_{0-2}-(\text{C}_{1-20}$ alkyl), $\text{S}(\text{O})_{0-2}-\text{aryl}$;

- $\text{S}(\text{O})_{0-2}-(\text{C}_{1-20}$ alkyl), $\text{S}(\text{O})_{0-2}-\text{heteroaryl}$;

- $\text{S}(\text{O})_{0-2}-(\text{C}_{1-20}$ alkyl), $\text{S}(\text{O})_{0-2}-\text{heterocyclyl}$;

- $\text{N}(\text{R})_2$;

- NR_3 ;

- halogen;

- NO_2 ;

- OR; and

- SH; and

- C_{1-20} alkyl, $\text{NR}_2-\text{Q}-\text{X}-\text{R}_4$ or $-\text{C}_{2-20}$ alkenyl, $\text{NR}_2-\text{Q}-\text{X}-\text{R}_4$ wherein Q is $=\text{C}(\text{O})-$ or $=\text{SO}_2-$; X is a bond, $=\text{O}-$ or $=\text{NR}_3-$ and R_4 is aryl; heteroaryl; heterocyclyl, or - C_{1-20} alkyl or C_{2-20} alkenyl that is unsubstituted or substituted by one or more substituents selected from the group consisting of:

- aryl;

- heteroaryl;

- heterocyclyl;

- $\text{O}-\text{C}_{1-20}$ alkyl;

- $\text{O}-\text{C}^{\text{a}}(\text{R})_{2-}\text{alkyl}$, $\text{O}-\text{aryl}$;

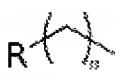
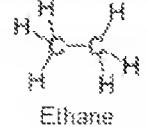
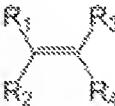
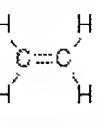
- $\text{O}-\text{C}^{\text{a}}(\text{R})_{2-}\text{alkyl}$, $\text{O}-\text{heteroaryl}$;

- $\text{O}-\text{C}^{\text{a}}(\text{R})_{2-}\text{alkyl}$, $\text{O}-\text{heterocyclyl}$;

According to the definitions given in Wikipedia, alkenyl is a unsaturated linkage.

See below,

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Chemical class	Group	Formula	Structural Formula	Prefix	Suffix	Example
Alkane	Alkyl	RH		alkyl-	-ane	 Ethane
Alkene	Alkenyl	$R_2C=CR_2$		alkenyl-	-ene	 Ethylene (Ethene)
Alkyne	Alkynyl	$RC\equiv CR'$		alkynyl-	-yne	 Acetylene (Ethyne)

Applicants claim includes Z to be - CH=CH-

The Dellaria reference clearly teaches the unsaturated linkage with a phenyl group.

Gerster teaches generically and Dellaria has species with the unsaturated linkage with the phenyl Ar.

The compounds have the same use. The compounds reduced to practice have alimited scope and clearly are obvious over the prior art reference given.

The rejection therefore is maintained.

The ODP rejection over 11/570707 in view of Gerster '340 and Kato is maintained as applicants have not provided any convincing arguments nor have they provided a TD.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, flex time..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rita J. Desai/
Primary Examiner, Art Unit 1625

May 5, 2010.